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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,349	09/01/2005	Lars R. Damgaard	HOI-13302/16	2540
25/006 7590 03/17/2009 GIFTORD, KRASS, SPRINKLE, ANDERSON & CITKOWSKI, P.C PO BOX 7021 TROY, MI 48007-7021				
EXAMINER				
MARTIN, PAUL C				
ART UNIT		PAPER NUMBER		
1657				
MAIL DATE		DELIVERY MODE		
03/17/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/540,349

Applicant(s)

DAMGAARD ET AL.

Examiner

PAUL C. MARTIN

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 27,36-38,40,42,43,45,48,49,51-53,57,60-67 and 70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,8,10,12,13,21,30,31,68 and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1-3,8,10,12,13,21,27,30,31,36-38,40,42,43,45,48,49,51-53,57,60-68,70 and 71.

DETAILED ACTION

Claims 1-3, 8, 10, 12, 13, 21, 27, 30, 31, 36-38, 40, 42, 43, 45, 48, 49, 51-53, 57, 60-68, 70 and 71 are pending in this application, Claims 27, 36-38, 40, 42, 43, 45, 48, 49, 51-53, 57, 60-67 and 70 are acknowledged as withdrawn, Claims 1-3, 8, 10, 12, 13, 21, 30, 31, 68 and 71 were examined on their merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/15/09 has been entered.

The rejection of Claims 1-3, 8, 10, 12, 13, 21, 30, 31, 68 and 71 under 35 U.S.C. § 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, has been withdrawn due to the Applicant's amendments to Claim 1 in the Supplemental Amendment filed 02/12/09.

The rejection of Claims 1-3, 8, 10, 12, 13, 21, 30, 31, 68 and 71 under 35 U.S.C. § 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which Applicant regards as the invention, has been withdrawn due to the Applicant's amendments to Claim 1 in the Supplemental Amendment filed 02/12/09 to correct the matter of insufficient antecedent basis.

The rejection of Claims 1, 8, 10, 13, 21, 30, 31, 68 and 71 under 35 U.S.C. § 102(b) as being anticipated by Miltenberger *et al.* (US 4,649,114) has been withdrawn due to the Applicant's amendments to Claim 1 in the Supplemental Amendment filed 02/12/09.

The rejection of Claims 1-3, 8, 10, 21, 30, 31, 68 and 71 under 35 U.S.C. § 102(b) as being anticipated by Wodnicka *et al.* (US 4,649,114) has been withdrawn due to the Applicant's amendments to Claim 1 in the Supplemental Amendment filed 02/12/09 and due to the persuasiveness of the Applicant's arguments filed 01/15/09 and 02/12/09.

The rejection of Claims 1-3, 8, 10, 21, 30, 31, 68 and 71 under 35 U.S.C. § 103(a) as being unpatentable over Miltenberger *et al.* (US 4,649,114) has been withdrawn due to the Applicant's amendments to Claim 1 in the Supplemental Amendment filed 02/12/09.

The rejection of Claims 1-3, 8, 10, 12, 13, 21, 30, 31, 68 and 71 under 35 U.S.C. § 103(a) as being unpatentable over Miltenberger *et al.* (US 4,649,114) in view of Schwarz *et al.* (US 5,763,279) has been withdrawn due to the Applicant's amendments to Claim 1 in the Supplemental Amendment filed 02/12/09.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8, 10, 13, 30, 31, 68 and 71 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Katerkamp *et al.* (US 6,730,471 B1).

Katerkamp teaches a culture device for monitoring metabolic activity comprising a Microwell™ plate (Column 5, Lines 31-37), wherein each cylindrical well is defined by an oxygen permeable membrane (Column 8, Lines 19-23 and Fig. 5), a stagnant culture medium (inherently having a viscosity greater than or equal to water) such that an oxygen diffusion gradient is established (Column 8, Lines 30-35 and Fig. 6) and an oxygen detector comprising an oxygen sensitive membrane (Columns 10 and 11, Claims 1-2).

Katerkamp *et al.* does not teach a device wherein the transverse dimension (interpreted by the Examiner as the diameter) of the wells of the Microwell™ is less than 1.5mm or wherein the well has an adjustable bottom operable to change the dimensions and either increase or decrease the well volume.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Katerkamp *et al.* which taught a device for the monitoring of metabolic activity in any microwell plate to use a microwell plate with wells having transverse dimensions of less than 1.5mm because the changing of the size of the well would have been a matter of artisan preference and does not patentably distinguish the claimed invention from the prior art.

The MPEP states:

In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Further, the modification of the method of Katerkamp *et al.* to make the device further comprise an adjustable bottom is *prima facie* obvious. The MPEP states:

In re Stevens, 212 F.2d 197, 101 USPQ 284 (CCPA 1954) (Claims were directed to a handle for a fishing rod wherein the handle has a longitudinally adjustable finger hook, and the hand grip of the handle connects with the body portion by means of a universal joint. The court held that adjustability, where needed, is not a patentable advance, and

because there was an art-recognized need for adjustment in a fishing rod, the substitution of a universal joint for the single pivot of the prior art would have been obvious.).

While the device of Katerkamp *et al.* is directed to the culture of cells, the limitation of an individual substantially spherical metabolizing particle (or cell) would not preclude the use of the device of Katerkamp for such a purpose. The MPEP states:

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997)

Claims 1-3, 8, 10, 12, 13, 21, 30, 31, 68 and 71 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Katerkamp *et al.* (US 6,730,471 B1) in view of Barker *et al.* (US 5,652,142).

The teachings of Katerkamp *et al.* were discussed above.

Katerkamp *et al.* does not teach a device comprising an insert for the adjustment of the transverse dimension of the compartment, or wherein a metabolite permeable layer is arranged in the bottom of the at least one compartment.

Barker *et al.* teaches a cell culture insert with a metabolite permeable layer at the bottom suitable for use with any a culture vessel with any number of wells (Column 3, Lines 15-47) and which permits a concentration gradient of nutrients to develop through the permeable membrane (abstract). It is inherent in the device of Barker *et al.* that the use thereof will result in a cell culturing compartment which has a smaller diameter than the culture well it is in.

It would have been obvious to one of ordinary skill in the art to combine the culture device of Katerkamp *et al.* for monitoring metabolic activity with the cell culture insert device of Barker *et al.* because doing so would allow one to create a concentration gradient of soluble nutrients/metabolites and gaseous metabolites in the culture well.

One of ordinary skill in the art would have been motivated to make this combination so as to advantageously monitor metabolism of both gas and soluble nutrients. There would have been a reasonable expectation of success in making this combination because both devices are drawn to cell culturing and the creation of concentration gradients.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Biran *et al.* "Optical Imaging Fiber-Based Single Live Cell Arrays: A High-Density Cell Assay Platform"; Analytical Chemistry, Vol. 74, No. 13 (2002) pp. 3046-3054.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL C. MARTIN whose telephone number is (571)272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

03/03/09

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657